DEC 2 1 2011 K113479

5.1. 510(k) Summary

The following 510(k) summary is submitted in accordance with the requirements of 21 CFR 807.92:

5.1.1. Applicant

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5.1.2. Contact Person

Alan Marquardt
Vice President of Regulatory, Clinical and Quality
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5.1.3. Date Prepared

July 1, 2011

5.1.4. Classification

Class II
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Classification Product Code: OOE
Classification Product Code Name: Ophthalmic Femtosecond Laser

5.1.5. Trade Name

OptiMedica Catalys™ Precision Laser System

5.1.6. Predicate Devices

LenSx 550 Laser System (LenSx Lasers Inc. Aliso Viejo CA); K094052

5.1.7. Intended Use

The OptiMedica Catalys™ Precision Laser System is indicated for anterior capsulotomy and laser phacofragmentation during cataract surgery. The anterior capsulotomy and phacofragmentation procedures may be performed either individually or consecutively during the same surgery.

5.1.8. Device Description

The Catalys™ Precision Laser System ("Catalys™ System" or "System") is an ophthalmic surgical laser system indicated for use in cataract surgery to create a precise anterior capsulotomy and/or to effect phacofragmentation, thus facilitating efficient lens removal. The System employs femtosecond ("FS") laser technology with integrated Optical Coherence Tomography ("OCT"), all of which are controlled and monitored by dedicated electronics. The System utilizes a common optical path for the OCT and femtosecond treatment laser (including the three-dimensional scanner and Liquid Optics™ [patient] Interface). As such, the beams are intrinsically co-registered and provide for precise overlap between imaging and treatment beams. In addition to the laser classifications per 21 CFR 1040.10 and 1040.11, the Catalys™ Precision Laser System complies with the requirements for Class I lasers per ANSI Z136.1-2007.

5.1.9. Substantial Equivalence

The OptiMedica Catalys™ Precision Laser System is substantially equivalent to the LenSx 550 Laser System in terms of indications for use, technological characteristics and performance specifications. The mechanism of laser cutting is the same for both systems in that the ultra-short laser pulses create a highly localized plasma and subsequent cavitation event that when controlled by a computerized scanning system direct the laser beam through a three dimensional pattern to produce a precise capsulotomy and effectively fragment the crystalline lens. Furthermore, the Catalys™ System incorporates an integrated spectral domain optical coherence tomography (OCT) sub-system to guide the laser treatment effectively.

5.1.10. Summary of Bench, Animal and Clinical Performance Testing

Bench testing of the Catalys™ System was conducted to demonstrate the OCT sub-system's ability to measure depth, surface profiles and iris diameters with accuracy and precision. Various test article substrates of known dimensions were measured multiple times by the System's OCT sub-system. All OCT-measured values met the test protocol acceptance criteria of ±40µm for all thicknesses and diameters, and ± 1% for all surface radii. This testing verifies that the OCT subsystem of the Catalys™ System can measure depth, surface profiles and diameters accurately and precisely.

Bench testing of the Catalys™ System was also conducted to demonstrate the System's ability to deliver a variety of laser patterns intended for capsulotomy or phacofragmentation with corresponding accuracy and precision. In this test, all laser parameters such as spot spacing, depth spacing, and pulse energy were bracketed to

assess the full capability of the System. Additionally, the System's entire suite of capsulotomy and phacofragmentation patterns was similarly bracketed to test the full spectrum of physician-selectable pattern variations. Multiple samples for a given test pattern were created in a test substrate that was subsequently cross-sectioned and measured using a NIST-traceable reticule, under magnified digital image analysis. All measured values met the test protocol acceptance criteria of ±100µm relative to the intended cut dimensions. The spectrum of pattern testing validated the System capability to cut a variety of capsulotomy and phacofragmentation patterns within specified limits for accuracy and precision.

Animal testing was performed to demonstrate retinal and corneal safety, and to establish the strength of the lens post-capsulotomy.

The OptiMedica Catalys™ Precision Laser System was clinically evaluated in a prospective, randomized non-inferiority trial in which one eye was randomly assigned to receive treatment with the Catalys™ System, including capsulotomy and laser phacofragmentation, followed by standard ultrasound phacoemulsification as necessary. The subject's contralateral eye, serving as the study Control eye, was assigned treatment with the current "gold standard" surgical technique of continuous curvilinear capsulorrhexis (CCC) and standard ultrasound phacoemulsification. Catalys™ System treatment times for the combined capsulotomy and laser phacofragmentation were found to be less than one minute in all subjects. Total procedure time (defined as the total time the subject was under suction and docked to the System) averaged just over 5 minutes with a maximum of 14 minutes.

Capsulotomy effectiveness was determined by evaluating the accuracy of the laser capsulotomy compared to CCC surgical Control. Table 1 shows the difference between the intended and the actual diameter of the capsulotomy (all subjects treated with the Catalys™ System) versus capsulorhexis (Control).

Table 1 - Difference Between Actual and Intended Diameter

Difference from Intended Diameter	Catalys™ System	Control
Mean (µm)	29	339
Standard Deviation(µm)	26	248
Minimum(µm)	1	23
Maximum (µm)	132	1013

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Laser phacofragmentation effectiveness was determined by comparison of the Catalys™ System (all subjects) and surgical Control cohort's Cumulative Dissipated Energy (CDE) values reported at the conclusion of the cataract surgery. The CDE values represent the total ultrasound energy delivered during the phacoemulsification and are detailed in Table 2:

Table 2 - Cumulative Dissipated Energy (CDE) Values

CDE	Catalys™ System	Control
Mean	10.39	18.54
Standard Deviation	6.61	12.07
Minimum	0.91	5.23
Maximum	27.65	47.86

Safety of the Catalys™ System was evaluated by tallying all subject complications and adverse events and comparing these findings to those of the surgical Control cohort. Non-device-related complications and adverse events were found to be comparable between the two cohorts. Device-related complications ascribed to the Catalys™ System were limited to petechiae (72% of eyes) and subconjunctival hemorrhage (5% of eyes). All device-related complications were determined to be mild and transitory in nature, as all resolved in less than 30 days without the need for additional medical intervention.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 2 1 2011

OptiMedica Corporation
c/o Mr. Alan Marquardt
Vice President of Regulatory, Clinical and Quality
3100 Coronado Drive
Santa Clara, CA 95054

Re: K113479
Trade/Device Name: OptiMedica Catalys™ Precision Laser System
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: OOE
Dated: November 22, 2011
Received: November 23, 2011

Dear Mr. Marquardt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113479

Device Name: OptiMedica Catalys™ Precision Laser System

Indications For Use:

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Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K113479